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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 10/728,051 | 12/04/2003 | Michael J. Caplan | 2002834-0222 | 9832 |
| 7590 | 03/11/2005 | | | |
| EXAMINER | | | | HUYNH, PHUONG N |
| ART UNIT | | PAPER NUMBER | | |
| | | 1644 | | |
| DATE MAILED: 03/11/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/728,051 | CAPLAN, MICHAEL J. | |
| | Examiner | Art Unit | |
| | Phuong Huynh | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 December 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) _____ is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

- I. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
- II. Claims 1-33 are pending.

Election/Restrictions

- III. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 1. Claims 1-6 and 8-14, drawn to a method of treating an allergy in a subject susceptible to an anaphylactic allergic response by providing a composition comprising microorganisms that produce **peanut protein or polypeptide**, classified in Class 424, subclass 93.1.
 2. Claims 1-6 and 9-14, drawn to a method of treating an allergy in a subject susceptible to an anaphylactic allergic response by providing a composition comprising microorganisms that produce dairy product **milk protein or polypeptide**, classified in Class 424, subclass 93.1.
 3. Claims 1-6 and 9-14, drawn to a method of treating an allergy in a subject susceptible to an anaphylactic allergic response by providing a composition comprising microorganisms that produce dairy product **egg protein or polypeptide**, classified in Class 424, subclass 93.1.
 4. Claims 1-6 and 9-14, drawn to a method of treating an allergy in a subject susceptible to an anaphylactic allergic response by providing a composition comprising microorganisms that produce **seafood protein or polypeptide**, classified in Class 424, subclass 93.1.

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5. Claims 1-6 and 9-14, drawn to a method of treating an allergy in a subject susceptible to an anaphylactic allergic response by providing a composition comprising microorganisms that produce **nuts (other than peanut) protein or polypeptide**, classified in Class 424, subclass 93.1.
6. Claims 1-6 and 9-14, drawn to a method of treating an allergy in a subject susceptible to an anaphylactic allergic response by providing a composition comprising microorganisms that produce **fruit protein or polypeptide**, classified in Class 424, subclass 93.1.
7. Claims 1-5, 7 and 9-14, drawn to a method of treating an allergy in a subject susceptible to an anaphylactic allergic response by providing a composition comprising microorganisms that produce **bee venom protein or polypeptide**, classified in Class 424, subclass 93.1.
8. Claims 1-5 and 9-14, drawn to a method of treating an allergy in a subject susceptible to an anaphylactic allergic response by providing a composition comprising microorganisms that produce **latex protein or polypeptide**, classified in Class 424, subclass 93.1.
9. Claims 1-5, 10-11 and 14-15, drawn to a method of treating an allergy in a subject susceptible to an anaphylactic allergic response by providing a composition comprising microorganisms that produce the food allergen wherein said **allergen is a small molecule**, classified in Class 424, subclass 93.1.
10. Claims 1-5, 10-11 and 14-15, drawn to a method of treating an allergy in a subject susceptible to an anaphylactic allergic response by providing a composition comprising microorganisms that produce the venom wherein the **venom is a small molecule**, classified in Class 424, subclass 93.1.
11. Claims 1-5, 10-11 and 14-15, drawn to a method of treating an allergy in a subject susceptible to an anaphylactic allergic response by providing a composition comprising microorganisms that produce the latex allergen wherein the **latex is a small molecule**, classified in Class 424, subclass 93.1.

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12. Claims 16-22 and 24-33, drawn to a **composition** or a pharmaceutical composition comprising a **microorganism that produce peanut polypeptide** and a pharmaceutical carrier, classified in Class 424, subclass 93.1.
13. Claims 16-22 and 25-33, drawn to a **composition** or a pharmaceutical composition comprising a **microorganism that produce dairy product milk polypeptide** and a pharmaceutical carrier, classified in Class 424, subclass 93.1.
14. Claims 16-22 and 25-33, drawn to a **composition** or a pharmaceutical composition comprising a **microorganism that produce egg polypeptide** and a pharmaceutical carrier, classified in Class 424, subclass 93.1.
15. Claims 16-22 and 25-33, drawn to a **composition** or a pharmaceutical composition comprising a **microorganism that produce seafood polypeptide** and a pharmaceutical carrier, classified in Class 424, subclass 93.1.
16. Claims 16-22 and 25-33, drawn to a **composition** or a pharmaceutical composition comprising a **microorganism that produce polypeptide from nuts (other than peanut)** and a pharmaceutical carrier, classified in Class 424, subclass 93.1.
17. Claims 16-22 and 25-33, drawn to a **composition** or a pharmaceutical composition comprising a **microorganism that produce fruit polypeptide** and a pharmaceutical carrier, classified in Class 424, subclass 93.1.
18. Claims 16-21, 23 and 25-33, drawn to a **composition** or a pharmaceutical composition comprising a **microorganism that produce bee venom polypeptide** and a pharmaceutical carrier, classified in Class 424, subclass 93.1.
19. Claims 16-21 and 25-33, drawn to a **composition** or a pharmaceutical composition comprising a **microorganism that produce latex polypeptide** and a pharmaceutical carrier, classified in Class 424, subclass 93.1.

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20. Claims 16-21 and 25-32, drawn to a **composition** or a pharmaceutical composition comprising a food allergen wherein said **food allergen is a small molecule** and a pharmaceutical carrier, classified in Class 424, subclass 184.1.
21. Claims 16-21 and 25-32, drawn to a **composition** or a pharmaceutical composition comprising a venom allergen wherein **the venom allergen is a small molecule** and a pharmaceutical carrier, classified in Class 424, subclass 184.1.
22. Claims 16-21 and 25-32, drawn to a **composition** or a pharmaceutical composition comprising a latex allergen wherein **the latex allergen is a small molecule** and a pharmaceutical carrier, classified in Class 424, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-11 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. In the instant case, the methods of treating different allergic diseases with different products (microorganism that produced modified allergen from different source versus small molecule) which differ with respect to their process steps and endpoints. Therefore, they are patentably distinct. Further, the distinct steps and products require separate and distinct searches. Even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited. A prior art search also requires a literature search.

Inventions of Groups 12-22 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products as claimed differ with respect to structure and physiochemical properties. Therefore, they are patentably distinct. A prior art search also requires a literature search. Because a search of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the examiner.

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Inventions of Groups (12-22) and Groups (1-11) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in materially different process such as making antibody or screening assays. Therefore, they are patentably distinct. A prior art search also requires a literature search. Because a search of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the examiner.

- IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods comprising the distinct method steps. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.
- V. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- VI. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.**

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

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examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

- VII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.
- VIII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

March 4, 2005


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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